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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-15-0052; NOP-15-12]

RIN 0581-AD43

National Organic Program (NOP);

Sunset 2016 Amendments to the National List

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule addresses recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following their April 2015 meeting. These recommendations pertain to the 2016 sunset review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the recommendations from the NOSB, this final rule removes five nonorganic nonagricultural substances from the National List for use in organic handling: egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate when their use exemptions (allowances) expire on September 12, 2016.

DATES: *Effective Date:* This rule is effective on September 12, 2016.

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SUPPLEMENTARY INFORMATION:

I. Background

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the USDA organic regulations, as indicated in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by the OFPA, the NOSB develops recommendations to amend the National List. The NOSB operates in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to assist in the evaluation of substances to be used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. The OFPA also requires a sunset review of all substances included

on the National List within five years of their addition to or renewal on the list. If a listed substance is not reviewed by the NOSB and renewed by the USDA within the five year period, its allowance or prohibition on the National List is no longer in effect. Under the authority of the OFPA, the Secretary can amend the National List through rulemaking based upon proposed amendments recommended by the NOSB.

The NOSB's recommendations to continue existing exemptions and prohibitions include consideration of public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s) as required by the OFPA. Recommendations to either continue or discontinue an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)) are determined by the NOSB's evaluation of technical information, public comments, and supporting evidence that demonstrate that the substance is: (a) harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; or (c) inconsistent with organic farming and handling practices.

In accordance with the sunset review process published in the Federal Register on September 16, 2013 (78 FR 61154), this final rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB on April 30, 2015, to amend the National List to remove five substances allowed as ingredients in or on processed products labeled as "organic." The exemptions of each substance appearing on the National List for use in organic production and handling are evaluated by the NOSB using the evaluation criteria specified on the OFPA (7 U.S.C. §§ 6517 – 6518).

II Overview of Amendments

Nonrenewals

After considering public comments and supporting documents, the NOSB determined that one substance allowed on § 205.605(a) and four substances allowed on § 205.605(b) of the National List are no longer necessary or essential for organic handling. The NOSB concluded that practices and other substances are suitable alternatives to egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate. AMS has reviewed and accepts the five NOSB recommendations for removal. Based upon these NOSB recommendations, this action amends the National List to remove the exemptions for egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate when their use exemptions expire on September 12, 2016.

Egg white lysozyme

The USDA organic regulations include an exemption on the National List for egg white lysozyme as a nonsynthetic ingredient for use in organic processed products at § 205.605(a) as follows: egg white lysozyme (CAS # 9001-63-2). In 2004, egg white lysozyme was petitioned for addition to § 205.605 because it was considered to be an essential processing aid/preservative for controlling bacteria that survived the pasteurization process of milk that is used for cheese manufacture. As recommended by the NOSB, egg white lysozyme was added to the National List on September 12, 2006 (71 FR 53299). The NOSB recommended the renewal of egg white lysozyme during their 2011 sunset review and the listing was renewed in a final rule published on August 3, 2011 (76 FR 46595). The NOSB completed the 2016 sunset review for the allowance of egg white lysozyme at their April 2015 meeting.

AMS published two notices of the NOSB public meetings covering the 2016

sunset review, in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975) with requests for comments. Their purpose was to notify the public that the allowance for egg white lysozyme would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substances included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the documents: AMS–NOP–14–0063 (October 2014 NOSB public meeting) and AMS – NOP-15-0002 (April 2015 NOSB public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the AMS website at <http://www.ams.usda.gov/nop>. During their sunset review of egg white lysozyme the NOSB considered two technical reports on enzymes that were requested by and developed for the NOSB in 2011 and 2003, which are also available for review on the AMS website.

Public comments provided the NOSB with information about the availability of practice-based alternatives to the use of egg white lysozyme. Such comments provided limited information to support the continued need for egg white lysozyme in organic processed products. Based on those public comments, the NOSB determined that the allowance for egg white lysozyme on the National List in § 205.605(a) is no longer necessary or essential for organic processed products. Subsequently, the NOSB recommended removal of egg white lysozyme from the National List at their April 2015 public meeting.

A proposed rule to remove egg white lysozyme from the National List was published on December 16, 2015 (80 FR 78150). AMS received comments that egg white lysozyme is used in the organic processing of beer, wine and hard cheeses. The prevalence of use in organic processing could not be ascertained from the public comments. Further, the comments did not assert that egg white lysozyme is essential in organic processing. Therefore, consistent with the NOSB recommendation, this final rule amends § 205.605(a) by removing the allowance for egg white lysozyme. This amendment is effective on egg white lysozyme's sunset date, September 12, 2016. After that date, egg white lysozyme will be prohibited in organic processing.

Cyclohexylamine, Diethylaminoethanol and Octadecylamine

The USDA organic regulations include allowances on the National List for cyclohexylamine, diethylaminoethanol and octadecylamine as processing aids for use in organic processing at § 205.605(b) as follows:

Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization.

Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization.

Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization.

Cyclohexylamine, diethylaminoethanol and octadecylamine were added to the National List on September 12, 2006 (71 FR 53299). The NOSB recommended the renewal of cyclohexylamine, diethylaminoethanol and octadecylamine during their 2011 sunset review. AMS published a notice renewing the allowances for cyclohexylamine,

diethylaminoethanol and octadecylamine the National List on August 3, 2011 (76 FR 46595).

Subsequently, the NOSB considered the allowances for cyclohexylamine, diethylaminoethanol, and octadecylamine during the 2016 sunset review. AMS published two notices in the Federal Register announcing the NOSB public meetings and requesting public comments on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). Their purpose was to notify the public that the allowances for cyclohexylamine, diethylaminoethanol and octadecylamine would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substances included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document: AMS–NOP–14–0063 (October 2014 NOSB meeting) and AMS–NOP-15-0002 (April 2015 NOSB meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the AMS website at <http://www.ams.usda.gov/nop>. During their 2016 sunset review, the NOSB considered technical reports on cyclohexylamine, diethylaminoethanol, and octadecylamine that were requested by and developed for the NOSB in 2001; these are available for review on the AMS website.

The September 2014 and April 2015 NOSB meeting notices requested information on the continued use of cyclohexylamine, diethylaminoethanol, or octadecylamine as boiler water additives in organic processing. Public comment in response to these requests informed the NOSB that organic processors are phasing out

these materials. The comments provided limited information supporting the continued need for the use of cyclohexylamine, diethylaminoethanol, or octadecylamine as boiler water additives. The NOSB cited information from public comments and the potential for adverse human health and environmental impacts in their conclusion that the allowances for cyclohexylamine, diethylaminoethanol, or octadecylamine on § 205.605(b) are no longer necessary or essential in organic processing. Therefore, the NOSB recommended that cyclohexylamine, diethylaminoethanol, and octadecylamine be removed from the National List.

AMS published a proposed rule with a request for comments on December 16, 2015 (80 FR 78150). No public comments were received supporting the continued use of cyclohexylamine, diethylaminoethanol, and octadecylamine in organic processing. Consistent with the NOSB recommendation, this final rule amends § 205.605(b) by removing the allowances for cyclohexylamine, diethylaminoethanol, and octadecylamine. This amendment is effective on cyclohexylamine, diethylaminoethanol, and octadecylamine's current sunset date, September 12, 2016. After that date, these substances are prohibited in organic processing.

Tetrasodium pyrophosphate

The USDA organic regulations include an exemption on the National List for tetrasodium pyrophosphate as an ingredient for use in organic processed products at § 205.605(b) as follows: Tetrasodium pyrophosphate (CAS # 7722-88-5)—for use only in meat analog products. In December 2001, tetrasodium pyrophosphate was petitioned for addition onto § 205.605 for use as an ingredient in organic food processing facilities. As recommended by the NOSB, tetrasodium pyrophosphate was added to the National List

on September 12, 2006 (71 FR 53299). In the 2011 sunset review, the NOSB recommended renewing the allowance for tetrasodium pyrophosphate. Consistent with the NOSB recommendation, AMS published a notice in the Federal Register renewing the tetrasodium pyrophosphate exemption on the National List on August 3, 2011 (76 FR 46595).

For the 2016 sunset review, AMS published two notices in Federal Register announcing the NOSB public meetings and requesting comments on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975). The notices informed the public that the tetrasodium pyrophosphate exemption would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary and to request information on the necessity of tetrasodium pyrophosphate as an ingredient in organic food processing. During their 2016 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2016 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document: AMS–NOP–14–0063 (October 2014 public meeting) and AMS–NOP-15-0002 (April 2015 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the AMS website at <http://www.ams.usda.gov/nop>. In addition, during their 2016 sunset review, the NOSB considered two technical reports on tetrasodium pyrophosphate that were requested by and developed for the NOSB in 2014 and 2002; these are available for review on the AMS website.

Public comment to the NOSB did not support a continued need for tetrasodium pyrophosphate in the production of organic processed products and informed that various alternative substances are available. Based on public comments and information in the 2014 technical report on tetrasodium pyrophosphate, the NOSB determined that there are alternatives to this substances that may be more compatible with organic production. Therefore, the NOSB determined that the allowance for tetrasodium pyrophosphate on § 205.605(b) is no longer necessary or essential for organic processed products and recommended that tetrasodium pyrophosphate be removed from the National List.

A proposed rule with a request for comments was published on December 16, 2015 (80 FR 78150), and no public comments were received supporting the continued use of tetrasodium pyrophosphate in processed organic products. Consistent with the NOSB recommendation, this final rule amends § 205.605(b) by removing the substance exemption for tetrasodium pyrophosphate. This amendment is effective on tetrasodium pyrophosphate's current sunset date, September 12, 2016. After that date, tetrasodium pyrophosphate will be prohibited in organic processing.

III. Related Documents

Two notices of public meetings with request for comments were published in Federal Register on September 8, 2014 (79 FR 53162) and on March 12, 2015 (80 FR 12975) to notify the public that substances included in the 2016 sunset review would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. The listings for egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate were added to the National List on September 12, 2006 (71 FR 53299). The proposed rule to remove the allowance for the

use of these substances in organic handling was published on December 16, 2015 (80 FR 78150).

IV. Statutory and Regulatory Authority.

OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The National List Petition Guidelines (NOP 3011) are published in the NOP Handbook which is available on the AMS website, <http://www.ams.usda.gov/nop>. This describes the information to be included for all types of petitions submitted to amend the National List.¹ AMS published a revised sunset review process in the Federal Register on September 16, 2013 (78 FR 56811).

A. Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly

¹ These guidelines supersede the "Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling," published January 18, 2007 in the Federal Register (72 FR 2167), which is now obsolete.

burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of OFPA. States are also preempted under sections 6503 through 6507 of OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 6507(b)(2) of OFPA, a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519(f) of OFPA, this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug

and Cosmetic Act (21 U.S.C. 301-399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 6520 of OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to prohibit the use of five nonorganic nonagricultural substances that have limited public support and may no

longer be used since nonorganic nonagricultural alternatives to these substances have been developed and implemented by food processors. AMS concludes that the economic impact of removing the nonorganic nonagricultural substance, egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate would be minimal to small agricultural firms since alternative practices and nonagricultural products may be commercially available. As such, these substances are proposed to be removed from the National List under this rule. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.6 million acres in 2014.² According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 19,470 in 2014. The list of certified operations is available on the NOP website at <http://apps.ams.usda.gov/nop/>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to

² U.S. Department of Agriculture, National Agricultural Statistics Service. September 2015. 2014 Certified Organic Productions Survey.

\$39.1 billion in 2014, an 11.3 percent growth over 2013 sales.³ In addition, the USDA has 80 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS website, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents report 31,020 certified operations worldwide in 2015⁴.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

E. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments received on Proposed Rule AMS-NOP-15-0052; NOP-15-12

AMS received nine comments from two consumers, one certifying agent, and six manufacturers (of organic products and ingredients used in organic products) on proposed rule AMS-NOP-15-0052. These written comments can be viewed at <http://www.regulations.gov> by searching for the document: AMS-NOP-15-0052.

³ Organic Trade Association. 2014. Organic Industry Survey. www.ota.com.

⁴ USDA, AMS, National Organic Program, Organic INTEGRITY Database, <https://apps.ams.usda.gov/integrity/>.

One comment presented general concerns about organic inspections that are not within the scope of this rule. One comment stated general opposition to all chemicals in organic production and agreed with the proposal to remove five nonorganic, nonagricultural substances from the National List.

Changes Requested But Not Made

The comments of a certifying agent and six manufacturers opposed the proposal to remove the allowance for egg white lysozyme in organic processing. These comments indicated that egg white lysozyme is used in the production of wine, beer and hard cheeses. The comments did not specify the prevalence of egg white lysozyme in organic processing or provide compelling information to explain why this substance is essential in organic processing. Therefore, AMS is implementing the NOSB recommendation to remove this substance from the National List.

No comments addressed the proposed removal of cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate.

Consistent with the NOSB recommendations, this final rule amends § 205.605 by removing egg white lysozyme, cyclohexylamine, diethylaminoethanol, octadecylamine, and tetrasodium pyrophosphate.

This amendment is effective on the current sunset date, September 12, 2016. After that date, these substances will be prohibited in organic processing.

List of Subjects in 7 CFR Part 205

Records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

§ 205.605 [Amended]

2. Amend § 205.605 by:

A. In paragraph (a), remove the substance “Egg white lysozyme (CAS # 9001-63-2)”.

B. In paragraph (b), remove the substances “Cyclohexylamine (CAS # 108-91-8)—for use only as a boiler water additive for packaging sterilization”; “Diethylaminoethanol (CAS # 100-37-8)—for use only as a boiler water additive for packaging sterilization”; “Octadecylamine (CAS # 124-30-1)—for use only as a boiler water additive for packaging sterilization”; and “Tetrasodium pyrophosphate (CAS # 7722-88-5)—for use only in meat analog products”.

Dated: July 26, 2016

Elanor Starmer
Administrator
Agricultural Marketing Service

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